UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

MAUREEN LUMBY	)	**Civil Action No.:** 4:17-cv-539
	)	
	)	
Plaintiffs,	)	
	)	**JURY TRIAL DEMANDED**
v.	)	
	)	
	)	
DAVOL INC., C.R. BARD INC., &	)	
RED OAK SALES, INC.	)	
	)	
Defendants.	)	
	)	
	)	

COMPLAINT

Comes now Plaintiff, Maureen Lumby (hereinafter "Plaintiff"), by and through undersigned counsel, and brings this action against Davol Inc., C.R. Bard Inc., & Red Oak Sales, Inc. (hereinafter "Defendants"), and alleges as follows:

Parties

1. Plaintiffs are, and were, at all relevant times, citizens and residents of Missouri and the United States.

2. Defendant C.R. Bard, Inc. ("Bard") is a foreign corporation with its principal office and place of business at 730 Central Avenue, New Providence, New Jersey 07974. At all times relevant herein, Bard was doing business in the State of Missouri and designed, manufactured, labeled, tested, distributed, advertised, marketed, promoted and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be permanently and surgically implanted in patients throughout the United States.

3. Defendant Davol Inc. ("Davol") is a foreign corporation with its principal place of business at 100 Crossing Boulevard, Warwick, Rhode Island 02886, and is a wholly owned subsidiary of Bard. At all times relevant herein, Davol was doing business in the State of Missouri and designed, manufactured, labeled, tested, distributed, advertised, marketed, promoted and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients throughout the United States.

4. Defendant Red Oak Sales, Inc. ("Red Oak") is incorporated and has its principal place of business in North Carolina and is a wholly owned subsidiary of Bard. Red Oak supplied polypropylene resin to Bard and/or Davol to manufacture various surgical hernia repair products, including the products at issue in the instant action. The polypropylene Red Oak purchased was knowingly provided by Red Oak to Bard/Davol for use in meshes sold in Missouri and throughout the United States.

Jurisdiction and Venue

5. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) as the parties are citizens of different States, and the amount in controversy exceeds the sum or value of $75,000.00, exclusive of interests and costs.

6. Venue is proper under 28 USC §1391(b)(2) in that a substantial part of the events or omissions giving rise to the claim occurred in this District. It is also proper under 28 USC §1391 (c)(2) in that Defendants are subject to the Court's personal jurisdiction because of substantial and continuous contacts within this District sufficient to subject it to personal jurisdiction, consisting of medical device sales and marketing on a substantial scale.

FACTUAL ALLEGATIONS

7. This action is brought within 5 years of Plaintiff's awareness of the mesh Products as the cause of her injuries and is within 5 years of the accrual of her cause of action within the meaning of RSMO §516.100 and §516.120(4) and *Elmore v. Owens-Illinois, Inc*, 673 SW2d 434, 436 (Mo. banc 1984).

8. Defendants Bard and Davol design, manufacture, market, package, label and sell medical devices, including the Composix E/X ("CEX") and the Ventrio Hernia Patch ("Ventrio") hernia repair medical devices (collectively "Products"), each of which was implanted in Plaintiff.

9. The design of these devices includes layers of heavyweight polypropylene mesh on one side, and expanded polytetraflouroethylene (ePTFE) on the other side. The ePTFE side is intended to allow for intra-peritoneal placement and is supposed to prevent adhesions between viscera and the device and/or damage to the viscera. As the body heals, the abdominal wall tissue grows into the polypropylene side of the mesh and scar formation occurs, which is supposed to strengthen the repair.

10. Synthetic meshes, like the CEX and Ventrio, are grouped as heavyweight or lightweight. The weight of the mesh depends on both pore size and the weight of the polymer and the amount of material used. The CEX and Ventrio are heavyweight meshes, which use thick polymers and have small pore size. Lightweight meshes are composed of thinner filaments and have larger pores.

11. At the time Defendants manufactured and distributed Plaintiff's device, Defendants knew or should have known the following regarding the heavyweight design of the CEX and Ventrio:

a. Mechanical stability of the heavyweight mesh in the CEX and Ventrio was too high and significantly exceeded physiological values of the abdominal wall.

b. Extensive fibrosis leads only to a stiffening of the implant and not to increased mechanical stability of hernia repair.

c. the greater foreign body load in the heavyweight mesh used in the CEX and Ventrio stimulates a greater inflammatory or fibrotic response leading to greater scar formation, decreased abdominal wall and graft compliance, decreased tissue incorporation, greater graft shrinkage, increased pain and increased risk of infection, failure of the repair, and other patient complications.

d. The greater the inflammatory response evoked by the mesh, the greater degree of contraction there will be, which can lead to hernia recurrence and/or visceral adhesions due to exposure of the bowel to the polypropylene layer.

e. Polypropylene is subject to oxidation, which is catalyzed by acids, bacteria and proinflammatory cytokines produced during the inflammatory reaction which can cause degradation and loss of compliance.

f. The weave of the CEX and Ventrio produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages.

g. Observation of mesh under the scanning electron microscope reveals that very small interstices exist between the mesh fibrils which are too small for a macrophage to

enter to destroy incubating bacteria. Some bacteria are capable of degrading polypropylene.

h. With loss of polypropylene due to degradation, the surface area is greatly increased thus providing greater areas for bacterial adherence and more elution of toxic compounds from the polypropylene and also the freed toxic polypropylene itself, all of which increases the inflammatory reaction and intensity of fibrosis.

i. Use of a larger pore size with less mesh material than was used in the CEX and Ventrio would result in less foreign body reaction and shrinkage. Pore size should be at least 3mm. The CEX and Ventrio pore size is much less than this; they have an effective porosity of 1mm.

j. That the heavyweight design in the CEX and Ventrio exposes patients to unique and significantly higher risks.

12. In other words, at the time Defendants manufactured and distributed Plaintiff's devices, Defendants knew or should have known using heavyweight versus lightweight mesh in the CEX and Ventrio did not provide any benefit to patients but did expose patients to increased risk when compared to lightweight mesh.

13. While publicly concealing and denying the dangers of the heavyweight design in its CEX and Ventrio, Defendants have now changed all of its hernia device designs from heavyweight mesh used in the CEX and Ventrio to lightweight mesh designs. This includes Bard's Soft Pore Mesh (cleared October 20, 2005), Composix L/P (cleared October 23, 2006), and the Ventralight ST Hernia Patch (cleared July 15, 2010). Bard's internal data confirms that these modified devices are substantially less likely to suffer mesh contraction and other

associated injuries. This data includes Defendants' internal testing on mesh contracture, host inflammatory and fibrotic response on these modified designs.

14. Further complicating the design of the CEX and Ventrio is the inclusion of an ePTFE layer, which has a higher shrinkage rate than the heavyweight polypropylene used in the CEX and Ventrio. Not only does this increase the amount of foreign body or inflammatory response, but the design also leads to the two sides of the mesh contracting at different rates and exposure of the polypropylene layer to the bowel.

15. At the time Defendants manufactured and distributed Plaintiff's device, Defendants had long known that the CEX and Ventrio were causing patients to suffer severe injuries including, inter alia, the following: perforation of the bowel, abnormal chronic enteric fistulae, infection, abscesses, bowel obstruction, chronic abdominal pain, peritonitis, sepsis, and adhesions between the bowel and the device. Defendants were further aware that these risks were either not present in other available devices or were substantially more likely with the CEX and Ventrio.

16. Upon information and belief Defendants failed to comply with the FDA application and reporting requirements.

17. Upon information and belief Defendants were aware of the high degree of complication and failure rates associated with the CEX and Ventrio.

18. Upon information and belief, Defendants were aware of the defects in the manufacture and design of the CEX and Ventrio and chose not to issue a recall of all of these products in the face of the high degree of complication and failure rates.

19. Upon information and belief, Defendants manipulated, altered, skewed, slanted, misrepresented, and/or falsified pre-clinical and/or clinical studies to bolster the perceived performance of the CEX and Ventrio.

20. Upon information and belief, Defendants paid doctors, surgeons, physicians, and/or clinicians to promote the CEX and Ventrio, but did not readily disclose this information.

21. Defendants failed to properly investigate and disclose adverse event reports to the FDA and other regulatory agencies worldwide regarding the CEX and Ventrio.

22. Defendants failed to implement adequate procedures and systems to report, track, and evaluate complaints and adverse events related to the CEX and Ventrio.

23. Defendants marketed the CEX and Ventrio to the medical community and to patients as safe, effective, reliable, medical devices for the treatment of hernia repair, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing mesh products. Defendants' did not undergo pre-market approval for the CEX and Ventrio and are therefore prohibited by the FDA from asserting superiority claims.

24. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the CEX and Ventrio.

25. Defendants failed to design and establish a safe, effective procedure for removal of the CEX and Ventrio; therefore, in the event of a failure, injury, or complications it is difficult to safely remove these devices.

26. Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using the CEX and Ventrio and

therefore increase its sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including the Plaintiff and his prescribing physician(s).

27. Plaintiff's hernia mesh device was utilized and implanted in a manner foreseeable to Defendants.

28. Plaintiff's hernia mesh device was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by the Defendants.

PLAINTIFF'S EXPERIENCE

29. On or about March 23, 2006, Plaintiff underwent a surgical hernia repair at North Kansas City Hospital in North Kansas City, Missouri by Dr. Mangesh Oza, who implanted the Composix E/X product into Plaintiff.

30. On or about July 3, 2012, Plaintiff underwent a revision procedure because the inconsistent contracture of the two materials in the Composix E/X had caused the graft to fold and, in part, pull away from the site of implantation.

31. In the course of the aforesaid revision procedure, Plaintiff was implanted with the Defendants' Ventrio product.

32. On or about October 3, 2015, Plaintiff underwent another revision procedure to remove the Ventrio product. In the course of the procedure, the surgeon noted that:

> "[t]here was a segment of the mesh that was folded and the non-PTFE side was exposed. There was small bowel adherent to this region…Three separate enterorrhaphies were required due to dense adhesions. Again, these enterorrhaphies were as a result of having to strip the bowel off the mesh."

33. The Products and the mesh used to manufacture the Products, at the time of implantation into Plaintiff, was defective and unreasonably dangerous, in that:

a) The Products and the mesh material degrades and therefore reacts with human tissues and/or other naturally occurring human bodily contents adversely affecting patient health.

b) The Products and the mesh material harbor infections that adversely affect human tissues and patient health.

c) The Products and the mesh material migrate from the location of their implantation, adversely affecting tissues and patient health.

d) The Products and the mesh material erode into surrounding structures, adversely affecting tissues and patient health.

e) The Products and the mesh material shrinks and/or contracts and hardens, adversely affecting tissues and patient health.

f) The Products and the mesh regularly fail to perform the purpose of their implantation such that the patient requires additional repair, removal of the device, and/or replacement of the device, all involving repeated treatment and surgery.

g) Due to their various defects, the Products and the mesh regularly cause significant injury to patients such that the Products must be removed, resulting in additional surgery and associated risks, pain, and tissue and nerve damage.

h) The Products and the mesh material provoke a foreign-body response, become embedded in human tissue over time, such that if it needs to be removed due to its various defects, complete removal is difficult or impossible, the removal poses significant risk of damage to organs, nerves and tissues, and results in additional scar tissue, adversely affecting patient health.

i) The Products and the mesh material provoke a foreign-body response that is patient specific and unpredictable, and necessarily involves inflammation. The foreign-body response involves growth and entrapment of nerves and nearby structures into the Products, and inflammation involves and aggravates nerves and nearby structures both grown into and surrounding the Products.

j) The resin used to make the mesh was not meant for medical applications involving permanent implantation in the human body.

k) The Products and the mesh material cause injury resulting in chronic severe debilitating pain.

l) The Products and the mesh material are defective in shape, composition, weight, physical, chemical and mechanical properties and are inappropriately engineered for use in the human body.

m) The risks of the Products and the mesh material do not outweigh the benefits as the risk of recurrence of the hernia is no better than with native tissue repairs and/or other hernia repair procedures.

n) The Products are defective in failing to warn, or failing to warn adequately, of the Products' potential dangers.

o) Plaintiff was implanted with the Products designed, manufactured, marketed, packaged, labeled, sold, and placed in the stream of commerce by Defendants, and as intended by Defendants. Prior to the time that the Products were implanted into Plaintiff, Defendants were aware of or should have been aware of numerous defects in the Products. Despite being aware of the numerous defects and unreasonable risks

associated with their products, Defendants manufactured, marketed, and distributed the Products with the intent that it would be implanted in patients. Defendants were aware that implanting the Products in patients was likely to cause injury and harm to some patients into whom the Products were implanted. Defendants also failed to exercise reasonable care in determining the risks and potential adverse consequences of implanting the Products into patients, and failed to use reasonable care in disclosing to doctors the potential adverse consequences of implanting the Products into patients.

34. Defendants made public statements in the form of written product descriptions, product labels, promotional materials and other materials that asserted that implanting the Products in patients was safe and would not cause harm to patients. These statements were made with the intent that medical professionals and members of the public would rely upon them, with the intent that members of the public would pay for the Products and that the Products would be implanted in patients. When Defendants made these statements, Defendants knew or should have known that the statements were inaccurate.

35. Representatives of Defendants also made statements to numerous individuals, including but not limited to medical professionals, that implanting the Products in patients was safe and would not cause harm to patients. When Defendants' representatives made these statements, Defendants knew or should have known that the statements were inaccurate.

36. Defendants knowingly and deliberately made material misrepresentations or did not disclose information to the United States Food and Drug Administration concerning the design, manufacture, safety, efficacy, and risks of the Products.

37. Before Plaintiff suffered the injuries complained of herein, Defendants were on notice of numerous bodily injuries caused by the Products, and based thereon, Defendants knew or should have known that the Product risks included migration, erosion, infection, perforation, shrinkage and/or contraction, chronic severe debilitating pain, degradation, scarring, nerve entrapment, nerve damage, disfigurement, adhesion formation, and other complications and injuries including the risks associated with additional removal surgeries in men implanted with the Products.

38. Even though Defendants have known or should have known that the Products created foreseeable, unreasonable risks of harm to those patients in whom it was implanted, Defendants continued to market the Products, failed to adequately test and investigate these risks and did not warn or failed to adequately warn of the risks associated with the Products.

39. Defendants have either never warned or provided only inadequate warnings or information of the risks associated with the Products.

COUNT I: NEGLIGENCE
MAI 25.09

40. Plaintiff repeats and re-alleges the above paragraphs of the Complaint as though fully restated herein.

41. Defendants had a duty to use ordinary care in designing, manufacturing, testing, packaging, labeling, promoting, distributing and selling the Products for hernia repair. Defendants had a duty to keep abreast of scientific knowledge, discoveries, advances, and medical literature. Defendants had a duty to provide complete disclosure of all risks and the extent of the danger and severity of any potential injury involved with the Products.

42. Defendants failed to use ordinary care in designing, manufacturing, testing, packaging, labeling, warning of risks, promoting, distributing and selling the Products for hernia repair.

43. Even after Defendants knew or should have known of the unreasonable, dangerous side effects, as well as other severe and permanent health consequences, Defendants failed to provide warnings, or to provide adequate warnings, and continued to market the Products.

44. Defendants failed to use ordinary care in failing to warn or instruct Plaintiff and/or his health care providers of the risks and the extent of the danger and severity of potential injuries involved with the Products.

45. Defendants knew or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in designing, manufacturing, testing, packaging, labeling, promoting, distributing and selling the Products.

COUNT II: STRICT PRODUCT LIABILITY

46. Plaintiff repeats and re-alleges the above paragraphs of the Complaint as though fully restated herein.

47. At all relevant times, Defendants together designed, manufactured, tested, packaged, labeled, promoted, distributed and/or sold the Products, and Plaintiff was a reasonably foreseeable or intended user or recipient of Defendants' Products. Defendants together exercised significant control over the aforementioned design, manufacture, packaging, or labeling of the Products.

Product Defect
MAI 25.04

48. Defendants sold the Products and/or the polypropylene resin making up the Products in the course of their businesses.

49. At the time of sale, the product and/ or the polypropylene resin making up the product were in a defective condition and unreasonably dangerous when put to a reasonably anticipated use.

50. The Products were used in a manner reasonably anticipated.

51. Such defective condition as existed when the product or the polypropylene resin was sold, caused or substantially contributed to cause the damages alleged herein.

Failure to Warn
MAI 25.05

52. Defendants sold the Products and/or the polypropylene resin making up theProducts in the regular course of their businesses.

53. At the time of sale, the Products and/or the polypropylene resin making up the Products were then unreasonably dangerous when put to a reasonably anticipated use without knowledge of their respective characteristics, for the reasons alleged herein.

54. Defendants failed to adequately warn of the risks alleged herein.

55. The Products were used in a manner reasonably anticipated.

56. The Products being sold without an adequate warning, caused or substantially contributed to cause the damages alleged herein.

COUNT III: BREACH OF WARRANTY
MAI 25.02 and 25.03

57. The Products were sold by Defendants as fit for permanent implantation in the human body and capable of fixing hernias. However, the Products failed to function as advertised and as represented by Defendants because they were not fit for permanent implantation in the human body for the reasons alleged herein and did not relieve the symptoms or otherwise alleviate the medical problems they are was intended to cure. In fact, the Products, for some patients, exacerbate and cause additional problems and the need for additional surgeries. Accordingly, the Products were not fit for the ordinary purpose for which such a good is used and failed to conform to representations of Defendants.

58. Furthermore, Defendants knew that the Products were to be used for the particular purpose for which they were used in Plaintiff and knew the expertise of Defendants was relied upon to furnish suitable goods.

59. The Products being unfit for the use for which they were purchased caused or substantially contributed to cause the damages alleged herein.

PUNITIVE DAMAGES
MAI 10.05

60. At the time Defendants sold the Products and the polypropylene from which it was made, Defendants knew of the defective and unreasonably dangerous nature of the Product and the polypropylene, and the inadequate warnings, and thereby showed complete indifference to, or conscious disregard for the safety of others, including Plaintiff, and such conduct warrants the imposition of punitive damages under all applicable legal standards.

WHEREFORE, plaintiff prays for a judgment for compensatory damages against all Defendants in such amount as is fair and reasonable under the circumstances, for prejudgment

interest, and for costs, as well as punitive damages in such sum as will serve to punish Defendants and deter Defendants and others from like conduct.

DEMAND FOR JURY TRIAL

The Plaintiff hereby demands a trial by jury on all Counts and as to all issues.

Dated: July 3, 2017

HOLLIS LAW FIRM, P.A.

/s/ Jason C. Chambers
Jason C. Chambers (MO Bar 62793)
Adam M. Evans (MO Bar 60895)
5100 W. 95th St.
Prairie Village, KS 66207
(913) 385-5400
(913) 385-5402 (fax)
jason@hollislawfirm.com

Attorneys for the Plaintiff